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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,005	08/29/2006	Fumio Matsuoka	13006.123	4835

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Fildes & Outland
Suite 2
20916 Mack Avenue
Grosse Pointe Woods, MI 48236

EXAMINER

FANG, SHANE

ART UNIT	PAPER NUMBER
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4131

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,005	Applicant(s) MATSUOKA ET AL.	
	Examiner SHANE FANG	Art Unit 4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08/29/06.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/29/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 1-2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending Application No. 11/629,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 1-2 are directed to an obvious variation of the invention as that of claims 1-2 of copending Application No. 11/629,264. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The only difference is ratio difference of polylactic acid vs. methacrylate. However, this ratio appears to merely determine the blending activity for the preparation

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of polyester blend. The normal desire of scientists or artisans to improve upon that is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages. **In re Peterson**, 315 F.3d at 1330, 65, USPQ2d at 1382. In this particular case, the motivation can be the optimizing properties of the resultant polyester blend by the optimizing the ratio of polylactic acid vs. methacrylate.

3. Claims 9-11 and 15-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9-10 of copending Application No. 11/629,264. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 9-11 and 15-20 are directed to an obvious variation of the invention as that of claims 9-10 of copending Application No. 11/629,264. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 9-10 of the copending Application No. 11/629,264 are silent on "biodegradable" and method of producing molding as recited in instant claims 9-11 and 15-20. Instant claims 9-11 and 15-20 are product-by-process claims that are limited by and defined by the process. Determination of patentability is based on the product itself, not on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. **In re Thorpe**, 777 F. 2d 695, 698,277 USPQ 964,966 (Fed. Cir. 1985). See MPEP § 2113. In addition, polylactic

acid, recited and referred in claims 1-2 of the copending Application No. 11/629,264, is a well-known biodegradable polyester.

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7 and 12 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Wang et al. (US 5952433 A)**.

As to claims 1-3, *Wang et al.* discloses a biodegradable polyester composition comprising modified and unmodified polylactic acid (PLA), 2-hydroxyethyl methacrylate (HEMA), and peroxide (Example 1 and 2). The range of HEMA/PLA shown in the 3rd column of Table (Col 11, ll 50) is calculated as 0.08-3.42 /100, anticipating the claimed range of (meth)acrylic ester/PLA. *Wang et al.* is silent on gelation index and melt viscosity. In view of the substantially identical composition, the adduct would possess the claimed crystallization properties. Since the PTO does not have proper means to conduct experiments, the burden of proof is now shifted to applicants to show

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otherwise. **In re Best**, 562 F. 2d 1252, 195 USPQ 430 (CCPA 1977); **In re Fitzgerald**, 205 USPQ 594 (CCPA 1980). See MPEP § 2112.

As to claim 4, *Wang et al.* discloses a method of preparing biodegradable via polyester composition comprising PLA, HEMA, and peroxide (Example 1 and 2) and melt mixer or a kneader (Col 10, ll 5). The composition and gelation index recited in claim 4 are rejected for the same reason as applied to claim 1.

As to claim 5, the reference discloses the blend is prepared by a melt extrusion process (Col 9, ll 67). The reference further discloses monomers including HEMA and peroxide are injected (Col 8, ll 52-54) to be blended with PLA melt (Example 1). The reference is silent on using solution or dispersion of (meth)acrylic ester; however, using solution or dispersion of (meth)acrylic ester is merely for the monomer addition by (liquid) injection. HEMA is a liquid at room temperature, and it is considered a form of solution with broadest interpretation.

As to claim 6, the reference discloses injecting peroxide (from barrel #6) after HEMA (from barrel #5) to PLA melt (from barrel #1-#4) are mixing in melt (Example 1). Further mixing and kneading are carried out in sequential barrels (#7- #14) (Example 1).

As to claim 7, the reference discloses injecting HEMA (from barrel #5) to PLA melt (from barrel #1-#4) in the down stream region in the extruder (Example 1). Note the twin-screw extruder appears to have identical structural description as the kneader recited in claim 7. The gelation index recited in claim 7 is rejected for the same reason as applied to claim 1.

Claim 12 is rejected via the rationales applied to claim 6 and claim 7.

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4. Claims 8-11 and 13-20 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over **Deckwer et al. (US 5952433 A)**.

Decker et al. discloses biologically degradable polyesters that can be processed, for example by thermoplastic processes such as compression moulding, extrusion, coextrusion, injection moulding, melt spinning, thermoforming, foaming or blow moulding into flat material, e.g. films, or into moulded parts or, by suitable methods, into foamed moulded parts, laminates, filamentous materials, fibres or composite materials (Col4, ll 42-48).

Claims 8-11 and 13-20 are product-by-process claims that are limited by and defined by the process. Determination of patentability is based on the product itself, not on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. **In re Thorpe**, 777 F. 2d 695, 698,277 USPQ 964,966 (Fed. Cir. 1985). See MPEP § 2113.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHANE FANG whose telephone number is (571)270-7378. The examiner can normally be reached on Mon.-Thurs. 8 a.m. to 6:30 p.m. EST..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Sample can be reached on (271)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ling-Siu Choi/
Primary Examiner, Art Unit 1796

s.f